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510(k) Summary

JAN 22 2013

PERMASORB™ Disposable Fixation Device

03 December, 2012

Submitter	Davol Inc. Subsidiary of C.R Bard, Inc 100 Crossing Boulevard, Warwick, RI 02886	**Contact**	Radhika Pondicherry Senior Regulatory Affairs (401)-825-8464 Fax (401)825-8764
Preparation Date	03 December, 2012		
Device Name			
Trade Name	PermaSorb™ Disposable Fixation Device		
Common/Classification Name	Staple, Implantable		
Regulatory Class	Class II per 21 CFR §878.4750		
Product Code	GDW		
Legally Marketed Predicate Device(s)	• K060494 Medchannel EasyTac Anchor- 03Jul2006 • K111153 SorbaFix™ Absorbable Fixation and PermaFix™ Fixation System- 24May2011		
Device Description	PermaSorb™ is endoscopic or open surgical stapler composed of a disposable sterile single use delivery instrument and resorbable fixation devices.		
Indications for Use	The PERMASORB™ Disposable Fixation Device is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.		
Device Modification	The ONLY modification is the addition of the following contraindications: 1. 'Do not use this device where hemostasis cannot be verified visually after application.' 2. 'Carefully inspect the area in the vicinity of the tissue being fastened to avoid inadvertent penetration of underlying structures such as nerves, vessels, viscera or bone. Use of the PERMASORB™ Disposable Fixation Device in the close vicinity of such underlying structures is contraindicated. For reference, the total length of the fastener (including the head) is 6.4mm.'		
Predicate Comparison	The PermaSorb™ Disposable Fixation Device is substantially equivalent to the predicate device cleared in K060494, with respect to indications for use, operating principles, materials, basic design, shelf life, packaging and sterilization. The Permasorb Disposable Fixation Device contains similar contraindications referenced in K111153.		
Non-Clinical Test Summary	No changes to product design specifications were made.		
Clinical Test Summary	No clinical studies were performed.		
Conclusions	PermaSorb™ Disposable Fixation Device is substantially equivalent to the predicate devices.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 22, 2013

C.R. Bard, Inc.
% Davol Inc.
Ms. Radhika Pondicherry
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K123718
Trade/Device Name: PermaSorb™ Disposable Fixation Device
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: January 04, 2013
Received: January 07, 2013

Dear Ms. Pondicherry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K123718

Device Name: PermaSorb™ Disposable Fixation Device

The PERMASORB™ Disposable Fixation Device is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123718